

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference A06022-PCT	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2006/314250	International filing date ( <i>day/month/year</i> ) 19 July 2006 (19.07.2006)	Priority date ( <i>day/month/year</i> ) 20 July 2005 (20.07.2005)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ASTELLAS PHARMA INC.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report 22 January 2008 (22.01.2008)	
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Authorized officer  Masashi Honda e-mail: pt08.pct@wipo.int

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL SEARCHING AUTHORITY

**TRANSLATION**  
**PCT**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

To:	Date of mailing (day/month/year)	
Applicant's or agent's file reference <b>A06022-PCT</b>		FOR FURTHER ACTION See paragraph 2 below
International application No. <b>PCT/JP2006/314250</b>	International filing date (day/month/year) <b>19.07.2006</b>	Priority date (day/month/year) <b>20.07.2005</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>ASTELLAS PHARMA INC.</b>		

1. This opinion contains indications relating to the following items:
<input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application
2. <b>FURTHER ACTION</b>
If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.
If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.
For further options, see Form PCT/ISA/220.
3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2006/314250

Box No. I	Basis of this opinion
	<p>1. With regard to the language, this opinion has been established on the basis of:</p> <p><input checked="" type="checkbox"/> the international application in the language in which it was filed</p> <p><input type="checkbox"/> the translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).</p> <p>2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:</p> <p>a. type of material</p> <p><input type="checkbox"/> a sequence listing</p> <p><input type="checkbox"/> table(s) related to the sequence listing</p> <p>b. format of material</p> <p><input type="checkbox"/> on paper</p> <p><input type="checkbox"/> in electronic form</p> <p>c. time of filing/furnishing</p> <p><input type="checkbox"/> contained in the international application as filed</p> <p><input type="checkbox"/> filed together with the international application in electronic form</p> <p><input type="checkbox"/> furnished subsequently to this Authority for the purposes of search</p> <p>3. <input type="checkbox"/> In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.</p> <p>4. Additional comments:</p>

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2006/314250

Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																									
<p><b>1. Statement</b></p> <table> <tr> <td align="center">Novelty (N)</td> <td align="center">Claims</td> <td align="center">1 – 7</td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td></td> <td align="center">NO</td> </tr> <tr> <td align="center">Inventive step (IS)</td> <td align="center">Claims</td> <td align="center">1 – 7</td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td></td> <td align="center">NO</td> </tr> <tr> <td align="center">Industrial applicability (IA)</td> <td align="center">Claims</td> <td align="center">1 – 7</td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td></td> <td align="center">NO</td> </tr> </table>		Novelty (N)	Claims	1 – 7	YES		Claims		NO	Inventive step (IS)	Claims	1 – 7	YES		Claims		NO	Industrial applicability (IA)	Claims	1 – 7	YES		Claims		NO
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	Claims		NO																						
Industrial applicability (IA)	Claims	1 – 7	YES																						
	Claims		NO																						
<p><b>2. Citations and explanations:</b></p> <p>Document 1: WO 2005/039542 A1 (Yamanouchi Pharmaceutical Co., Ltd.), 06 May 2005      Document 2: WO 02/096392 A1 (CIMA LABS INC.), 05 December 2002      Document 3: JP 2000-514830 A (Pfizer Pharmaceuticals Inc.), 07 November 2000      Document 4: JP 2004-26675 A (Lion Corp.), 29 January 2004      Document 5: JP 6-219939 A (McNeil-PPC, Inc.), 09 August 1994      Document 6: JP 6-316536 A (McNeil-PPC, Inc.), 15 November 1994      Document 7: JP 2002-272817 A (McNeil-PPC, Inc.), 24 September 2002</p>																									
<p>&lt;Claims 1-7&gt;</p> <p>The inventions of claims 1-7 are not disclosed in any of the documents cited in the ISR and appear to possess novelty and involve an inventive step.</p> <p>In particular, none of documents 1-7, which are the most relevant prior art documents, discloses that an intrabuccally disintegrating preparation that contains drug-containing coated fine particles having an average particle size of no more than 350 µm coating with a coating film comprising drug-containing fine particles containing a homogenously-mixed drug and polyethyleneglycol coated with water-soluble polymer, further comprising (1) a pH-independent water-insoluble polymer comprising at least 60% and less than 79% of the coating film and (2) hydroxypropyl cellulose comprising more than 21% and no more than 40% of the coating film, enables adequate suppression of an unpleasant taste in the mouth and rapid elution in the gastrointestinal tract.</p>																									